



## **Patient Information About FORTOVASE (FOR-toe-vase)**

### **FORTOVASE®**

#### **(saquinavir) Soft Gel Capsules**

#### **Generic Name: Saquinavir (sa-KWIN-a-veer)**

**ALERT: Find out about medicines that should NOT be taken with FORTOVASE.** Please also read the section **MEDICINES YOU SHOULD NOT TAKE WITH FORTOVASE.**

Please read this product information carefully before you start taking FORTOVASE and each time you renew your prescription. There may be new information. Reading this information can help you take this medicine correctly. However, it is not a substitute for your doctor's advice about the safety and benefits of FORTOVASE. You should talk to your doctor about FORTOVASE as part of your long-term treatment plan for HIV before you start taking your medication and ask any questions you may have at regular checkups. Remember, you should remain under a doctor's care when using FORTOVASE and should not change or stop your therapy without talking to your doctor first.

#### ***What is FORTOVASE?***

FORTOVASE belongs to a class of anti-HIV medicines called protease (PRO-tee-ase) inhibitors. FORTOVASE Soft Gel Capsules in combination with other anti-HIV drugs are used for the treatment of HIV, the virus that causes AIDS (acquired immunodeficiency syndrome).

#### ***How does FORTOVASE work?***

FORTOVASE fights HIV as it grows inside cells by blocking an enzyme (protease) that HIV needs to reproduce.

#### ***How is FORTOVASE different from INVIRASE® (saquinavir mesylate)?***

Both FORTOVASE and INVIRASE contain the same active ingredient—saquinavir. When FORTOVASE or INVIRASE are taken two times a day with ritonavir, a similar amount of saquinavir gets into the blood to fight HIV. However, FORTOVASE can be taken three times a day without ritonavir and the correct amount of saquinavir can get into the blood.

INVIRASE should never be taken without ritonavir. FORTOVASE may be taken without ritonavir if you are not able to tolerate even a small amount of ritonavir.

You should not substitute one for the other. If the medicine you receive does not look like the beige soft gel capsule (FORTOVASE) in the patient information, it is not the correct drug. Talk to your doctor, nurse or pharmacist if you are not sure that you have the correct medication.

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### ***Who should not take FORTOVASE?***

Anyone who has had a severe allergic reaction to FORTOVASE or any of the ingredients in the capsule should not take it. The use of FORTOVASE in patients under 16 years of age, over 65 years of age, or those with serious liver problems has not been fully investigated.

### ***How should FORTOVASE be taken?***

- The recommended dosage of FORTOVASE in combination with anti-HIV medications is six capsules three times a day. The recommended dosage of FORTOVASE in combination with Norvir® (ritonavir) is FORTOVASE 5 capsules two times a day taken with 1 capsule of Norvir two times a day. In some combinations, your dose may change. If you cannot tolerate Norvir (ritonavir) then your doctor will tell you the dose of FORTOVASE that is right for you.
- FORTOVASE must be taken with meals or up to 2 hours after a meal—but it is easiest to remember if you take it with your meals. When FORTOVASE is taken without food, the amount of FORTOVASE in the blood is lower and may not fight HIV as well.
- When taking FORTOVASE and other anti-HIV medicines, it is very important to follow the directions exactly and take your medication every day. If you skip doses—or take less than the prescribed dose—the medicine will not work as well, and your disease could get worse.
  - If you miss a dose, you should take the next dose as soon as possible. However, do not double the dose.

### ***What results have been seen with FORTOVASE?***

FORTOVASE has been shown to reduce the amount of virus in the blood (“viral load”) and increase CD<sub>4</sub> (T) cells when taken with other HIV therapy.

### ***What are the side effects of FORTOVASE?***

People treated with FORTOVASE in combination with other anti-HIV medications may have side effects. The majority of these have been described as mild. In clinical studies of patients who received FORTOVASE in combination with other HIV drugs the side effects seen most often were: diarrhea (16% to 20%), nausea (11% to 18%), abdominal discomfort (9% to 13%) and heartburn (8% to 9%).

Side effects occurring in 0.5% to 2% of patients in clinical studies included weight gain, gum disease, numbness or tingling, fever, convulsions, itching and rash, shortness of breath, fungal infection, hepatitis, night sweats, blurred vision and difficult urination. Side effects occurring rarely, in less than 0.5% of patients, and also considered serious, included dizziness, coughing blood, bleeding in the brain, ulcers, inflamed pancreas and rapid heart rate.

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Significant increases in liver function tests have been reported in 1.2% to 5.7% of patients taking FORTOVASE. Worsening of liver problems has also been reported in people with pre-existing liver disease.

People treated with FORTOVASE and ritonavir may have side effects. In clinical studies of patients who received FORTOVASE in combination with ritonavir and other HIV drugs the side effects seen most often were: nausea (10.8%), vomiting (7.4%), tiredness (6.1%), stomach pain (6.1%), body fat changes (5.4%), pneumonia (5.4%), and diarrhea (6.8%).

Diabetes (new onset or worsening) and increased blood sugar levels have been reported with the use of protease inhibitors. In addition, increased bleeding in patients with hemophilia has also been associated with these drugs.

When saquinavir is taken with ritonavir, some patients may experience large increases in triglyceride and cholesterol levels. The long-term chance of getting complications such as heart attack or stroke due to increases in triglyceride and cholesterol levels caused by protease inhibitors is not known at this time.

Changes in body fat have been seen in some patients taking anti-HIV medications. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breasts, and around the body. Loss of fat from the legs and arms may also happen. The cause and long-term health effects of these conditions are not known at this time.

These are not the only side effects that can occur with FORTOVASE. Your doctor can discuss with you a more complete list of side effects and laboratory abnormalities that may accompany this medication.

If any side effects or unusual symptoms do occur, contact your doctor immediately. Do not stop or decrease your dose on your own. Lowering the dose may make FORTOVASE less effective in fighting HIV.

### ***Are there other medications that I should not take with FORTOVASE?***

There are some drugs that should not be taken with FORTOVASE. Before starting therapy with FORTOVASE, be sure to tell your doctor all of the medicines—prescription medications, as well as over-the-counter drugs and nutritional supplements—that you are now taking or plan to take.

### ***MEDICINES YOU SHOULD NOT TAKE WITH FORTOVASE***

| Drug Class         | Drugs Within Class Not to Be Taken with FORTOVASE  |
|--------------------|--|
| Antiarrhythmics    | Pacerone® (amiodarone), Tambocor® (flecainide), Rhythmol® (propafenone), bepridil, quinidine |
| Antihistamines     | Seldane® (terfenadine)*, Hismanal® (astemizole)*   |
| Antimigraines      | Ergot medications (eg, Wigraine® and Cafergot®)  |
| GI motility agents | Propulsid® (cisapride)*  |

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|--------------------------|---|
| Sedatives, hypnotics     | Versed® (midazolam), Halcion® (triazolam) |
| Antimycobacterial agents | Rifampin                                  |
| Neuroleptics             | Pimozide                                  |

\* No longer sold in the US.

FORTOVASE causes increased blood levels of these compounds. This can lead to serious or life-threatening reactions such as irregular heartbeat or prolonged sedation.

Taking FORTOVASE with St. John's wort (*hypericum perforatum*), an herbal product sold as a dietary supplement, or products containing St. John's wort is not recommended. Talk with your doctor if you are taking or are planning to take St. John's wort. Taking St. John's wort may decrease FORTOVASE levels and lead to increased viral load and possible resistance to FORTOVASE or cross-resistance to other antiretroviral drugs.

Garlic capsules should not be used while taking FORTOVASE as the sole protease inhibitor due to the risk of decreased saquinavir in the blood. No data are available for the co-administration of FORTOVASE and Norvir with garlic capsules or INVIRASE and Norvir with garlic capsules.

Your doctor may want to change your medicine if you are taking rifampin (known as Rifadin®, Rifamate®, Rifater® or Rimactane®) or Mycobutin® (rifabutin); these drugs substantially reduce the level of FORTOVASE in the blood.

The following drugs increase blood levels of FORTOVASE: Norvir® (ritonavir)\*, Viracept® (nelfinavir)§, Rescriptor® (delavirdine)§||, Nizoral® (ketoconazole), Crixivan® (indinavir)§ and Biaxin® (clarithromycin).

Talk to your doctor if you are taking lipid (cholesterol) lowering drugs and Viagra® (sildenafil citrate), Levitra® (vardenafil), and Cialis® (tadalafil).

### ***Does FORTOVASE cure HIV/AIDS?***

FORTOVASE does not cure AIDS, and it does not prevent you from getting other illnesses that result from advanced HIV infection. In addition, FORTOVASE has not been shown to reduce the risk that you may transmit HIV to others through sexual contact or infected blood. You must continue to follow all of your doctor's recommendations for managing your illness.

### ***What else should I discuss with my doctor?***

Inform your doctor:

- If you are pregnant or become pregnant while taking FORTOVASE. The effects of FORTOVASE on pregnant women or unborn babies are not yet fully known. In addition, experts advise against breast-feeding if you are HIV positive, to reduce the risk of passing the virus to your baby.

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- If you are taking anti-HIV medications. Your doctor may want to change one or more of your anti-HIV drugs in order to achieve the best results when you start treatment with FORTOVASE.
- If you have diabetes or a family history of diabetes, or if you have hemophilia, hepatitis or other liver disease, your doctor should decide if FORTOVASE is right for you.
- If you have ever taken INVIRASE, discuss with your doctor whether FORTOVASE is right for you.

### ***How is FORTOVASE supplied?***

FORTOVASE is available as beige-colored soft gel capsules in a 200-mg strength. FORTOVASE comes in bottles of 180 capsules.

### ***How should I store FORTOVASE?***

Refrigerated 2° to 8°C (36° to 46°F) capsules of FORTOVASE remain stable until the expiration date on the bottle. Once brought to room temperature (at or below 25°C or 77°F), capsules should be used within 3 months. If you live in a hot climate or your home is hot in the summer, you should keep FORTOVASE refrigerated. Capsules should not be frozen. The bottles should be kept tightly closed.

FORTOVASE has been prescribed specifically for you, and only for a particular condition. Do not use it for anything else. Do not give it to anyone else. If you think you have taken more than your prescribed dose, seek medical attention.

**Keep this medication and all other medications out of the reach of children.** Do not keep medicine that is out of date or that you no longer need. Be sure that if you throw any medicine away, it is out of the reach of children.

This provides only a brief summary of product information about FORTOVASE. If you have any questions about FORTOVASE or HIV, talk to your doctor.

† Below the amount that could be found using a standard test.

‡ Dosages greater than 100 mg twice a day of ritonavir when taken in combination with saquinavir were associated with an increase in side effects.

§ The safety and efficacy of FORTOVASE in combination with these drugs has not been established. Dosage adjustments may be required.

|| Use of this combination should be accompanied by close monitoring of liver enzymes.

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*If you have any questions about FORTOVASE, call toll free at 1-800-910-4687, or visit our Web site at [www.FORTOVASE.com](http://www.FORTOVASE.com).*



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